2 510(k) Summary

MAR 2 0 2012

[As required by 21 CFR 807.92]

510(k) Number: K112100 **Date Prepared: July 19, 2011**

Submitter's Information / Contact Person

Manufacturer
Vascular Solutions, Inc.
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Establishment Registration # 2134812

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General Information

Trade Name	M2 Navigation Catheter and GuideLiner Navigation Catheter
Common / Usual Name	Percutaneous catheter
Classification Name	21 CFR 870.1250, Percutaneous Catheter
Predicate Device	GuideLiner Catheter (K091750 - Vascular Solutions, Inc.)

Device Description

The M2 Navigation catheter and GuideLiner Navigation catheter (Navigation catheters) are rapid-exchange catheters with a working length of 163 cm. The device is available in eight sizes and is compatible with GuideLiner catheters (GuideLiner Navigation catheter models) and 6F, 7F, and 8F guide catheters (M2 Navigation catheter models).

The distal portion of the device is a 25 cm single-lumen catheter that serves as the guidewire lumen. Portions of the outer diameter (OD) of the lumen are cross shaped to allow blood to flow around the catheter while staying centered within a guide catheter or GuideLiner catheter. The device is compatible with 0.014 inch exchange length or 180 cm guidewires. The catheter lumen is constructed with two durometers of Pebax (polyether block amide) resin over a polyimide-PTFE

composite liner. The device has one radiopaque marker band located 2 mm from the distal tip. The OD of the lumen has a silicone wipe to enhance deliverability to the target vasculature. The proximal end of the lumen transitions to a 304V stainless steel pushwire that has non-radiopaque positioning marks located at 95 cm (single mark) and 105 cm (double mark) from the distal tip. A short Pebax hub/sleeve covers the proximal end of the pushwire.

Intended Use / Indications

Navigation catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of guidewires and other interventional devices.

Technological Characteristics

Navigation catheters and predicate GuideLiner devices have the same design components consisting of a proximal hub, push wire, and distal lumen. Minor dimensional differences reflect the additional sizes for compatibility of the Navigation catheters with various guide catheters and GuideLiner catheters. Minor material changes were also implemented to increase the lumen flexibility, provide a longer, distal tip that tapers, and simplify device manufacturing.

Inner diameters (ID) of Navigation catheters differ from the predicate GuideLiner catheter. The smaller IDs of Navigation catheters allow for a tapered tip design. The OD of Navigation catheters are cross shaped while the OD of GuideLiner catheters are round.

Substantial Equivalence and Summary of Studies

Navigation catheters are substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design was qualified through the following tests:

- Visual inspections for:
  - label legibility, wear, or smudging
  - sharp edges, points, irregularities
  - lubricious wipe
- Dimensional verifications
- Positioning mark tape test
- Simulated anatomy/concomitant device use
- Kink
- Bond tensile
- Torque

A biomaterial assessment concluded that biocompatibility testing was not required based on the similarity of materials and manufacturing processes utilized in the predicate device and other devices manufactured by Vascular Solutions, Inc. Results of the verification testing met the specified acceptance criteria and did not raise new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 2 0 2012

Vascular Solutions, Inc.
c/o Mr. Matt Nienstedt
Regulatory Product Specialist
6464 Sycamore Court
Minneapolis, MN 55369

Re: K112100
Trade/Device Name: M2 Navigation Catheter and GuideLiner Navigation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 1, 2012
Received: February 2, 2012

Dear Mr. Nienstedt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. A. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112100

Device Name: M2 Navigation Catheter and GuideLiner Navigation Catheter

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

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